

FORM PTO 1390  
(REV 5-93)

US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NUMBER  
2005\_0097ATRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. §371U.S. APPLICATION NO.  
(if known, see 37 CFR 1.5)  
10/524,024International Application No.  
PCT/JP2004/007894International Filing Date  
June 1, 2004Priority Date Claimed  
June 10, 2003

## Title of Invention

PATCH CONTAINING FENTANYL FOR MUCOUS MEMBRANE OF ORAL CAVITY

## Applicant(s) For DO/EO/US

Katsumi IHARA, Mitsuhiro NAGATA and Sayoko INAZUKI


Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. §371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. §371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. §371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. §371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. §371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. §371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19.
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. §371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. §371(c)(5)).

THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEES FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975

Items 11. to 14. below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ Other items or information:

|   |              |   |   |  |                     |
|---|--------------|---|---|--|---------------------|
| <b>U.S. APPLICATION NO.</b> (If known, see 37 CFR 1.5)<br>10/524,024  |              | <b>INTERNATIONAL APPLICATION NO.</b><br>PCT/JP2004/007894 |   | <b>ATTORNEY'S DOCKET NO.</b><br>2005_0097A |                     |
| 15. <input type="checkbox"/> The following fees are submitted   |              |   |   | <b>CALCULATIONS</b>                        | <b>PTO USE ONLY</b> |
| Basic National Stage Fee ..... \$300.00<br>National Stage Search Fee ..... \$500.00<br>National Stage Examination Fee ..... \$200.00<br>Specification/drawings in excess of 100 pages (units of 50 x \$250.00) = ..... \$   |              |   |   |  |                     |
| <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>   |              |   |   |  |                     |
| Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).   |              |   |   | \$   |                     |
| Claims  | Number Filed | Number Extra  | Rate  |  |                     |
| Total Claims  | -20 =        |   | X \$50.00   | \$   |                     |
| Independent Claims  | - 3 =        |   | X \$200.00  | \$   |                     |
| Multiple dependent claim(s) (if applicable)   |              |   | + \$360.00  | \$   |                     |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |   |   | \$0.00                                     |                     |
| <input type="checkbox"/> Small Entity Status is hereby asserted. Above fees are reduced by 1/2.   |              |   |   | \$   |                     |
| <b>SUBTOTAL =</b>   |              |   |   | \$0.00                                     |                     |
| Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).  |              |   |   | + \$                                       |                     |
| <b>TOTAL NATIONAL FEE =</b>   |              |   |   | \$0.00                                     |                     |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +   |              |   |   | \$   |                     |
| <b>TOTAL FEES ENCLOSED =</b>  |              |   |   | \$0.00                                     |                     |
|   |              |   |   | Amount to be refunded                      | \$                  |
|   |              |   |   | Amount to be charged                       | \$                  |
| a. <input checked="" type="checkbox"/> A check in the amount of \$0.00 to cover the above fees is enclosed. A duplicate copy of this form is enclosed.<br>b. <input type="checkbox"/> Please charge my Deposit Account No. 23-0975 in the amount of \$_____ to cover the above fees.<br>A duplicate copy of this sheet is enclosed.<br>c. <input type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23-0975. |              |   |   |  |                     |
| <b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>  |              |   |   |  |                     |
| 19. CORRESPONDENCE ADDRESS<br><br><br><div style="text-align: center;"> <b>CUSTOMER NO.</b><br/> <b>000513</b> </div>   |              |   | By: <br>Michael R. Davis,<br>Registration No. 25,134<br><br>WENDEROTH, LIND & PONACK, L.L.P.<br>2033 "K" Street, N.W., Suite 800<br>Washington, D.C. 20006-1021<br>Phone: (202) 721-8200<br>Fax: (202) 721-8250 |  |                     |
| May 6, 2005   |              |   |   |  |                     |

[2005\_0097A]

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

:

Katsumi IHARA et al.

:

Docket No. 2005\_0097A

Serial No. 10/524,024

:

Filed February 9, 2005

:

PATCH CONTAINING FENTANYL FOR  
MUCOUS MEMBRANE OF ORAL CAVITYSUPPLEMENTAL INFORMATION DISCLOSURE STATEMENTCommissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEES FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application PCT/\_\_\_\_\_;  
and/or
- ☐ each reference previously cited in prior parent application Serial No.  
\_\_\_\_\_.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

**and thus no certification and/or fee is required.**

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

- (1) ☐ the certification of paragraph 2 below is provided, **or**  
(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and  
the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or  
b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
  - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
  - c. ☒ the concise explanation contained in the specification of the present application at pages 1 and 2,
  - d. ☒ the concise explanation set forth in the attached English language abstract,
  - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

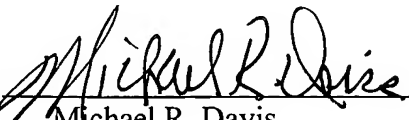
Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

7. ☒ Comments:

U.S. '580, cited on the attached PTO-1449 Form, corresponds to JP '725, also cited herein. US '866, cited herein, corresponds to JP '570, also cited herein. US '080, cited herein, corresponds to JP '066, cited on the PTO-1449 Form attached to the Information Disclosure Statement filed February 9, 2005.

Respectfully submitted,

Katsumi IHARA et al.

By   
Michael R. Davis  
Registration No. 25,134  
Attorney for Applicants

MRD/jmj  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
May 6, 2005

## INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)

Date Submitted to PTO: May 6, 2005

ATTY DOCKET NO.  
2005\_0097ASERIAL NO.  
10/524,024APPLICANT  
Katsumi IHARA et al.FILING DATE  
February 9, 2005

GROUP

## U.S. PATENT DOCUMENTS

| *EXAMINER<br>INITIAL |    | DOCUMENT<br>NUMBER | DATE    | NAME            | CLASS | SUBCLASS | FILING DATE IF<br>APPROPRIATE |
|----------------------|----|--------------------|---------|-----------------|-------|----------|-------------------------------|
|                      | AA | 4,588,580          | 5/1986  | Gale et al.     |       |          |                               |
|                      | AB | 6,139,866          | 10/2000 | Chono et al.    |       |          |                               |
|                      | AC | 2004/0180080       | 9/2004  | Furusawa et al. |       |          |                               |
|                      | AD |                    |         |                 |       |          |                               |
|                      | AE |                    |         |                 |       |          |                               |
|                      | AF |                    |         |                 |       |          |                               |
|                      | AG |                    |         |                 |       |          |                               |
|                      | AH |                    |         |                 |       |          |                               |
|                      | AI |                    |         |                 |       |          |                               |

## FOREIGN PATENT DOCUMENTS

|  |    | DOCUMENT<br>NUMBER | DATE   | COUNTRY | CLASS | SUBCLASS | TRANSLATION<br>YES NO |  |
|--|----|--------------------|--------|---------|-------|----------|-----------------------|--|
|  | AJ | 61-37725           | 2/1986 | JP      |       |          |                       |  |
|  | AK | 10-045570          | 2/1998 | JP      |       |          | Abstract              |  |
|  | AL |                    |        |         |       |          |                       |  |
|  | AM |                    |        |         |       |          |                       |  |
|  | AN |                    |        |         |       |          |                       |  |

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |   |
|--|----|---|
|  | AO | Abstract of JP 2000-44476 published February 15, 2000 |
|  | AP |   |
|  | AQ |   |

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of form with next communication to applicant.